MDA-19-125 5-028

110,00

Mr. Richard P. Spiller Vice President, Regulatory Affairs Xttrium Laboratories 415 W. Pershing Rd. Chicago, Illinois 60609

Dear Mr. Spiller:

Please refer to your supplemental New Drug Application (NDA) dated April 26, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Exidine (chlorhexidine gluconate) Topical Solution. 4%.

The supplemental application provide for the release of the reprocessed batch 512-1061-976.

We have completed our review of this supplemental application and it is approved effective as of the date of this letter.

Please submit to the file your report on the investigation of the reason/s for the failure and the corrective action/s you have implemented.

We acknowledge your commitment to place the lot of the marketed batch on stability and submit the results via annual reports.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely vours,

Suva B. Roy, Ph.D.

Team Leader, DNDC III

Division of Anti-infective Drug Products (HFD-520)

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

```
CC:Orig NDA 19-125/S-028

HFD-82

HFD-473

HFD-520

HFD-735

HFD-730

HFD-104

HFD-638

HFC-130/JAllen

HFD-520/DivDir/MFanning

HFD-520/MO/Bostwick

HFD-520/CSO/Dillon-Parker

HFD-520/MICRO/Sheldon

HFD-830/CHEM/Timper
```

HFD-830/SBRoy:R/D initialed

H	MIST'S REVIEW	⊥.	ORGAN	IZATION	2.	NDA NUMBER
ev	iew #1			(HFD-520		19-125
} .	NAME & ADDRESS OF	F APPL	ICANT	1		AF NUMBER
	Xttrium Laborator	ries				SUPPLEMENT
	415 W. Pershing I					MBER, DATE
	Chicago, IL 60609	9			SC	CS-028, 4/26/96
	(312) 268-5800					
•	NAME OF DRUG	7.	NONPR	OPRIETAR	Y NAME	
	Exidine		chlor	hexidine	glucona	ite
3.	SUPPLEMENT(s) PRO	OVIDES	FOR:	9	AMENDMEN	TTS AND OTHER
					n/a	
SCS	-028: The suppler	mental	appl	ication	provides	release of
:he	batch for reprod	cessin	g Lot	512-106	1-976, waa aubo	romient];;
	orhexidine glucor reased to a	nate s	OIULI T.O	t R512-1	vas subs 061-976	The reason
	the reprocessing	g was				1110 1000011
	the formulation.	, : -	J			
	PHARMACOLOGICAL	11	HOW	DISPENS	ED 12. F	RELATED
LU.	CATEGORY					ND/NDA/DMF(s)
	Antibacterial			xxx		
	AICIDACCCIIAI		Rx	OTC		
	DOSAGE FORM(s) 4% Topical Solut	ion				
	4% Topical Solut	ion AND ST	RUCTU	TRE · 2C ₆ H ₁₂ O ₇	, 897.7	
 15.	4% Topical Solut	ion AND ST	RUCTU	RE · 2C ₆ H ₁₂ O ₇ <u>16</u> .	, 897.7 RECORDS	7 S AND REPORTS
	4% Topical Solut	ion AND ST	RUCTU	RE · 2C ₆ H ₁₂ O ₇ <u>16.</u> CUR	, 897.7	AND REPORTS
	4% Topical Solut	ion AND ST	RUCTU	TRE 2C ₆ H ₁₂ O ₇ 16. CUR	, 897.7 <u>RECORDS</u> RENT	AND REPORTS
15.	4% Topical Solut CHEMICAL NAME A CAS-3697-42-5;	ion AND ST	RUCTU	TRE 2C ₆ H ₁₂ O ₇ 16. CUR:	, 897.7 <u>RECORDS</u> RENT X Yes	AND REPORTS
	CHEMICAL NAME A CAS-3697-42-5; COMMENTS n/a	AND ST	RUCTU	2C ₆ H ₁₂ O ₇ 16. CUR	, 897.7 RECORDS RENT X Yes IEWED X Yes	No No
15.	CHEMICAL NAME A CAS-3697-42-5; COMMENTS n/a Expedited revie	AND ST C ₂₂ H ₃₀ C	RUCTU	RE 2C ₆ H ₁₂ O ₇ 16. CUR: REV	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9	No No No REPORTS No No Reference of the second seco
L5.	CHEMICAL NAME A CAS-3697-42-5; COMMENTS n/a Expedited revie The approval le	AND ST C ₂₂ H ₃₀ C	RUCTU	RE $ \begin{array}{c} 2C_6H_{12}O_7\\ \underline{16.}\\ CUR.\\ REV \end{array} $ as grantests a fo	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9	No No No Of, S. Roy. report to be
.5.	CHEMICAL NAME A CAS-3697-42-5; COMMENTS n/a Expedited revie	AND ST C ₂₂ H ₃₀ C ew sta	RUCTU Cl ₂ N ₁₀ tus w reque corre	7 RE \cdot $2C_6H_{12}O_7$ $\frac{16}{CUR}$ \cdot \cdot \cdot REV \cdot \cdot as grantests a foliotive projective projective projective \cdot	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up	No No No No Report to be s, if
15.	CHEMICAL NAME A CAS-3697-42-5; COMMENTS n/a Expedited revie The approval le submitted to re necessary, to a	ew sta	tus wreques	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a folloctive precoverage	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up	No No No No Report to be s, if
15.	CONCLUSIONS AND	AND ST C ₂₂ H ₃₀ C ew sta etter eport addres D RECO	tus wreque corresthe	RE 2C ₆ H ₁₂ O ₇ 16. CUR: REV as grantests a for ctive precoverage	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of isor	No No No No Report to be s, if
15.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a conclusions and Recommend approximately.	ew stater eport address oval o	tus wreque corresthe	RE 2C ₆ H ₁₂ O ₇ 16. CUR: REV as grantests a for ctive precoverage	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of isor	No No No No Report to be s, if
15.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a CONCLUSIONS AND Recommend approprig: NDA 19-12	ew stater address oval o	tus wreques the	RE 2C ₆ H ₁₂ O ₇ 16. CUR: REV as grantests a for ctive precoverage	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of isor	No No No No Report to be s, if
L7.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a conclusions and Recommend approximately.	ew stateter eport address	tus wreque corres the	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a for coverage ATIONS s supples 20/Bostw	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of isor ment.	No No No No Report to be s, if
17.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a conclusions and Recommend approval 19-12 HFD-520 HFD-520/Sheldon	ew sta etter eport addres oval o	tus wreque corres the	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a foctive proverage ATIONS s supples 20/Bostw HFD-520/	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of ison ment. ick/MO Dillon-E	No No No No No Report to be a service of the properties of the pro
17.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a CONCLUSIONS AND Recommend approvag: NDA 19-12 HFD-520	ew sta etter eport addres oval o	tus wreque corres the	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a for coverage ATIONS s supples 20/Bostw	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of ison ment. ick/MO Dillon-E	No No No No No Report to be a service of the properties of the pro
15.	COMMENTS n/a Expedited revies the approval lessary, to a conclusions and Recommend approvations: NDA 19-12 HFD-520/Sheldon HFD-520/JTimper	ew stateter eport addres O RECO OVAL O 25 n/Micr	tus wreques the MMEND f thi HFD-5	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a for coverage ATIONS s supplements and coverage 20/Bostw HFD-520/ 20/SBRoy	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of ison ment. ick/MO Dillon-E	No No No No No No No Report to be a service of the properties of t
15. 17.	COMMENTS n/a Expedited revies the approval lessubmitted to renecessary, to a conclusions and Recommend appropriate NDA 19-12 HFD-520 HFD-520/Sheldon HFD-520/JTimper TE	ew stateter eport addres O RECO OVAL O 25 n/Micr	tus wreques the	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a for coverage ATIONS s supplements and coverage 20/Bostw HFD-520/ 20/SBRoy	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of ison ment. ick/MO Dillon-E	No N
15. 17.	COMMENTS n/a Expedited reviet The approval less submitted to renecessary, to a CONCLUSIONS AND Recommend approvag: NDA 19-12 HFD-520 HFD-520/Sheldon HFD-520/JTimper	ew stateter eport addres O RECO OVAL O 25 n/Micr	tus wreques the MMEND f thi HFD-5	RE 2C ₆ H ₁₂ O ₇ 16. CUR REV as grantests a for coverage ATIONS s supplements and coverage 20/Bostw HFD-520/ 20/SBRoy	, 897.7 RECORDS RENT X Yes IEWED X Yes ed 6/6/9 llow-up ocedures of ison ment. ick/MO Dillon-E	No No No No No No No Report to be a service of the properties of t